K121890

AUG 2 2 2012

5. 510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number _____.

Date Prepared: June 26, 2012

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Lorna K. Linville
Director, Regulatory Affairs
Telephone: (727) 399-5396
Fax (727) 399-5264

C. Device Name

Trade Name:	GENESYS PressFT™ Suture Anchor
Common Name:	Bioabsorbable Suture Anchor
Classification Name:	Fastener, Fixation, Biodegradable, Soft tissue
Proposed Class/Device:	Class II
Product Code:	MAI
Regulation:	21 CFR Part 888.3030

D. Predicate/Legally Marketed Devices

Device Name:	ConMed Linvatec NANO™ Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K112965

Device Name:	ConMed Linvatec CrossFT™-BC Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K101100

E. Device Description

The ***ConMed Linvatec GENESYS PressFT™ Suture Anchor*** is a device that is used to assist the surgeon in reattaching soft tissue to bone. The device includes anchors manufactured of 96L/4D copolymer + β-TCP and one (1) or two (2) Hi-Fi® sutures manufactured of ultra-high molecular weight polyethylene. The device is bioabsorbable and is available in two sizes: 1) a 2.5mm diameter x 9.8mm length suture anchor that is

utilized with a 2.1mm drill bit, and 2) a 3.0mm diameter x 10.6mm length suture anchor that is utilized with a 2.6mm drill bit. A disposable inserter is included to implant the suture anchor.

The disposable inserter device has a stainless steel shaft with a polycarbonate handle that is provided sterile, for single use and is removed at the end of the repair leaving behind the suture anchor construct. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period. Additional surgical instruments, including drill bits, guides and obturators, are Class I, non-sterile, reusable devices intended for transient use during orthopedic procedures.

F. Testing

The verification and validation testing of the GENESYS PressFT™ Suture Anchor includes fixation strength, cyclic loading, insertion, driver strength, biocompatibility, sterilization, shelf-life, and packaging qualifications.

G. Intended Use / Indications

The GENESYS PressFT™ Suture Anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period. Additional indications include acetabular labral repair and capsular repair in the hip.

H. Conclusion

The GENESYS PressFT™ Suture Anchor is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the ConMed Linvatec NANO™ Suture Anchor (K112965) and the ConMed Linvatec CrossFT™-BC Suture Anchor (K101100).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ConMed Linvatec
% Ms. Lorna K. Linville
Director, Regulatory Affairs
11311 Concept Boulevard
Largo, Florida 33773-4908

AUG 2 2 2012

Re: K121890
Trade/Device Name: Genesys PressFT Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: MAI
Dated: July 27, 2012
Received: July 30, 2012

Dear Ms. Linville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic & Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121896

Device Name: GENESYS PressFT Suture Anchor

Indications for Use:

The GENESYS PressFT Suture Anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue in conjunction with appropriate postoperative immobilization, throughout the healing period. Additional indications include acetabular labral repair and capsular repair in the hip.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121890